Protocol

Medical Services Protocol Updates

Distribution Date: **June 1, 2015**

The following Medical Protocol update includes information on protocols that have undergone a review over the last several months for annual review, or an additional review in order to make changes. The annual review may have resulted in a revision to the guidelines or no changes at all. Six new protocols have been added and four have been archived.

Please note that portions of this protocol update may not pertain for the members to whom you provide care.

Protocol Revision Summary

The effective date of these changes is July 1, 2015, unless otherwise indicated:

Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

Changes:

- Medically necessary criteria was added for the use of continuous ambulatory monitors that record and store information for periods longer than 48 hours;
- One medically necessary indication was added for patients with cryptogenic stroke who have had a negative standard work-up for atrial fibrillation including a 24-hour Holter monitor under the policy statement addressing use of implantable ambulatory event monitors, either patient-activated or auto-activated.

For Medicare Advantage:

- Medically necessary criteria for telephonic EKG transmissions was adjusted, now including initiation and directing of arrhythmic drug therapy and post hospital monitoring of patients discharged after myocardial infarction (MI); (only if 24-hour coverage is provided).

Bio-Engineered Skin and Soft Tissue Substitutes

Changes:

- One policy statement was expanded to include EpiFix® as a skin substitute that may be considered medically necessary for the treatment of chronic, non-infected, full-thickness diabetic lower extremity ulcers;
- Several skin and soft tissue substitutes were added to the list of products considered investigational.

Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure

Changes:

- Edits were made to New York Heart Association (NYHA), class III or IV, and class II criteria in a medically necessary policy statement;
- One new medically necessary policy statement was added for patients who do not meet the NYHA criteria;
- The investigational statements regarding patients with heart failure with atrial fibrillation and patients with NYHA class I heart failure had the phrase 'who do not meet the above criteria' added for clarification;
- A policy guidelines section was added to supply policy definitions;
- Additional background information was added.

Catheter Ablation of the Pulmonary Veins as Treatment for Atrial Fibrillation
Changes:

- Title was changed to *Catheter Ablation as Treatment for Atrial Fibrillation*;
- The phrase "in the pulmonary veins," as the specific foci for treatment of atrial fibrillation, was removed from the investigational policy statements;
- Information was added to the policy guidelines to detail the variations on procedures for catheter ablation of arrythmogenic foci.

Chromosomal Microarray Testing for the Evaluation of Early Pregnancy Loss
Changes:

- The title was changed to *Chromosomal Microarray Testing for the Evaluation of Early Pregnancy Loss and Intrauterine Fetal Demise* as the scope of the policy was expanded to address CMA testing for pregnancy loss at all gestational ages.
- A new policy statement was added to indicate that chromosomal microarray (CMA) testing of fetal tissue may be considered medically necessary for third trimester pregnancy losses;
- The investigational policy statement was rephrased to clarify the definition of early pregnancy and to include 'in all other situations';
- Additional information was included in the policy guidelines to address genetic counseling and to add definitions for the terms fetal tissue, early pregnancy loss, and intrauterine fetal demise.

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid
Changes:

- All material, including the investigational policy statement, addressing the use of artificial pancreas devices was removed from this protocol to create a separate protocol entitled *Artificial Pancreas Device Systems*;
- Information was added to the policy guidelines section regarding age as a criterion for the use of continuous glucose monitoring (CGM) devices.

Cosmetic vs. Reconstructive Surgery or Services
Change:

- All references to gender reassignment were removed from this protocol as the new *Gender Reassignment Surgery* protocol was adopted. This includes deletion of the Benefit Application section and the reference to gender reassignment not medically necessary services as criteria is defined in the new protocol.

Cytochrome p450 Genotyping
Changes:

- One policy statement was changed by adding examples of applications for which it is considered investigational to use CYP450 genotyping, including selection or dosage of codeine and the dosing of efavirenz;
- One policy statement was added indicating the use of genetic testing panels that include multiple CYP450 mutations is considered investigational.

Cytoreductive Surgery and Perioperative Intraperitoneal Chemotherapy for the Treatment of Pseudomyxoma Peritonei, Peritoneal Carcinomatosis of Gastrointestinal Origin and Peritoneal Mesothelioma
Changes:

- Title was changed to *Cytoreductive Surgery and Perioperative Intraperitoneal Chemotherapy for Select Intra-Abdominal and Pelvic Malignancies;*

- Medically necessary policy statements were reworded and combined with no change to intent;
- Clarification to the existing investigational policy statement on peritoneal carcinomatosis to indicate *from colorectal cancer, gastric cancer, or endometrial cancer*;
- Additions to the existing policy statement indicate that cytoreductive surgery and perioperative intraperitoneal chemotherapy are considered investigational for ovarian cancer and all other indications, including goblet cell tumors of the appendix;
- Background section updated with information related to ovarian cancer and peritoneal carcinomatosis.

Deep Brain Stimulation

Changes:

- A medically necessary policy statement was added which reads: Bilateral deep brain stimulation of the thalamus may be considered medically necessary in patients with disabling, medically unresponsive tremor in both limbs due to essential tremor or Parkinson disease;
- Alzheimer's disease was added as a disorder for which deep brain stimulation is considered investigational.

Dermatologic Applications of Photodynamic Therapy

Change:

- Terminology changed throughout protocol to reflect superficial basal cell carcinoma changed to low-risk (i.e., superficial or nodular) basal cell carcinoma and non-superficial basal cell carcinoma changed to high-risk basal cell carcinoma**.**

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Multiple changes in several policy statements to revise criteria for both adults and children, some changes are detailed here;

For general business:

- Medically necessary policy statement was added for screening of bariatric surgery patients;
- Detail was added to the medically necessary policy statement addressing auto –adjusting positive airway pressure (APAP) for pressure titration in adult patients by referencing the Apnea/Hypopnea Index (AHI) and the Respiratory Disturbance Index (RDI);
- Medically necessary situations in the policy statement addressing supervised polysomnography were reworded and clarified;
- An investigational policy statement for single, unattended sleep studies for adults with low-to-moderate risk for obstructive sleep apnea **(**OSA) was removed;
- Information was added to the policy guideline section related to the STOP-BANG questionnaire, OSA in children, Bariatric Surgery Patients, Polysomnography for Other Disorders, Multiple Sleep Latency Test, and Specialist Training;

For Medicare Advantage:

- One medically necessary statement for diagnostic testing was removed;
- A new medically necessary statement for diagnostic testing specific to OSA was added;
- A second medically necessary statement regarding coverage of a PAP device for treatment of OSA was re-worded and one criterion added;
- One not medically appropriate statement for patients with specific comorbidities was removed.

Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer
Changes:

- Title changed to *Genetic and Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer;*
- The original investigational policy statement was revised and clarified;
- A second investigational policy statement was created specifically addressing single nucleotide polymorphisms (SNPs) testing for cancer risk assessment of prostate cancer;
- Description/background information reorganized with information added.

Genetic Testing for Duchenne and Becker Muscular Dystrophy
Change:

- The statement regarding genetic testing for gene mutations for Duchenne Muscular Dystrophy in all other indications was clarified to read investigational instead of not medically necessary.

Genetic Testing for Hereditary Breast and/or Ovarian Cancer
Changes:

- Title was changed to *Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (BRCA1/BRCA2)*;
- All references to CHEK2 were removed from this protocol including the investigational policy statement;
- A medically necessary policy statement was removed as it addressed the type of testing (i.e., large genomic rearrangements) rather than patient selection/criteria for testing;
- Policy guidelines were expanded to include a recommended testing strategy and comprehensive mutation analysis sections;

For Medicare Advantage:

- Section was removed, no Medicare NCD or NYS LCD.

Hyperbaric Oxygen Pressurization (HBO)
Changes:

- Title changed to *Hyperbaric Oxygen Therapy*;
- The phrase 'in all other situations, included but not limited to' was added preceding a list of conditions for which hyperbaric oxygen pressurization is considered investigational;
- The term 'severe or refractory Crohn's disease' was changed to 'inflammatory bowel disease' in the investigational policy statement;
- The phrase 'except as noted earlier in the medically necessary statement' was added as a clarification in the investigational bullet point regarding radiation-induced injury in the head and neck;

For Medicare Advantage:

- Additional detail was added to the medically necessary policy statement regarding acute peripheral arterial insufficiency (added: covered when related to trauma, arterial embolism and thrombosis), osteoradionecrosis of the jaw (clarified: limited to cases with evidence of overt bony fracture or bony reabsorption), and added suturing of severed limbs.

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence
Changes:

- Cross-linked collagen was removed from the list of possible treatments in the medically necessary policy statement addressing treatment of stress urinary incontinence in men and women who have failed appropriate conservative therapy;

For Medicare Advantage:

- Additional informational statements added regarding skin testing for collagen sensitivity and provider training.

Intensity-Modulated Radiation Therapy (IMRT): Cancer of the Head and Neck or Thyroid

Changes:

- Title was changed to *Intensity-Modulated Radiotherapy (IMRT): Cancer of the Head and Neck or Thyroid*;
- One policy statement now reads that IMRT is not medically necessary for treatment of thyroid cancers for all indications not meeting the stated criteria.

Intraoperative Neurophysiologic Monitoring (Sensory-Evoked Potentials, Motor-Evoked Potentials, EEG Monitoring)

Change:

- Pertinent Medicare NCD has been retired; Medicare Advantage section has been deleted as there is no longer guidance to support it.

Islet Transplantation

Change:

- A second policy statement was added to indicate that islet transplantation is considered **investigational** in all other situations not defined in the previous policy statements.

KRAS and BRAF Mutation Analysis in Metastatic Colorectal Cancer

Changes:

- The title was changed *to KRAS, NRAS, and BRAF Mutation Analysis in Metastatic Colorectal Cancer*;
- A new policy statement was added to indicate NRAS mutation analysis to predict non-response to anti-EGFR monoclonal antibodies cetuximab and panitumumab in the treatment of metastatic colorectal cancer is investigational.

Laboratory Testing for HIV Tropism

Change:

- Criteria regarding viral replication and treatment history were removed from the medically necessary policy statement. The statement is now consistent with updated FDA prescribing information for maraviroc.

Low-Density Lipid Apheresis

Changes:

- The title of the policy was changed to *Lipid Apheresis*;
- One policy statement was added indicating therapeutic apheresis with selective high-density lipoprotein (HDL) delipidation and plasma reinfusion is investigational.

Magnetic Resonance Imaging-Guided Focused Ultrasound

Changes:

- One medically necessary policy statement was added addressing pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy;
- The investigational policy statement was changed by removing the new medically necessary indication (above) from this statement.

Negative Pressure Wound Therapy in the Outpatient Setting

Changes:

- The medically necessary policy statement under *Continuation of the powered NPWT* was clarified to specify that ongoing objective improvement during subsequent treatment is required;

For Medicare Advantage:

- The not medically necessary statements on quantity of supplies utilized were deleted as they were no longer supported by guidance;
- The first medically necessary statement was re-worded to clarify information on surgically created wounds and traumatic wounds.

Noninvasive Prenatal Testing for Trisomy 21 Using Cell-Free Fetal DNA

Changes:

- Title was changed to *Noninvasive Prenatal Testing for Fetal Aneuploidies Using Cell Free Fetal DNA*;
- One medically necessary policy statement was added to address concurrent nucleic acid sequencing-based testing of maternal plasma for trisomy 13 and/or 18 in women who are eligible for and are undergoing nucleic acid sequencing-based testing of maternal plasma for trisomy 21;
- One policy statement was added indicating nucleic acid sequencing-based testing of maternal plasma for trisomy 13 and/or 18, other than in the situations earlier specified is investigational;
- One policy statement was added indicating that nucleic acid sequencing-based testing of maternal plasma for fetal sex chromosome aneuploidies is investigational.

Outpatient Pulmonary Rehabilitation

Changes:

- One medically necessary policy statement was added for pulmonary rehabilitation programs following lung transplantation;
- One investigational policy statement was added for pulmonary rehabilitation programs following other types of lung surgery, included but not limited to lung volume reduction surgery and surgical resection of lung cancer.

Scintimammography/Breast-Specific Gamma Imaging/Molecular Breast Imaging

Changes:

- Title was changed to *Scintimammography and Gamma Imaging of the Breast and Axilla*;
- One investigational policy statement was added which addresses preoperative or intraoperative sentinel lymph node detection using handheld or mounted mobile gamma cameras**.**

Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Changes:

- One not medically necessary policy statement was added addressing surgical treatment of OSA in adults not meeting stated criteria;
- One investigational policy statement was added addressing implantable hypoglossal nerve stimulators for all indications;
- The criterion 'or failed an adequate trial of an oral appliance (OA)' was added to both medically necessary statements regarding surgical treatment of OSA in adults;
- Some rephrasing of medically necessary statements was done;
- Duplicative information on AHI and RDI parameters for both adult and pediatric populations was removed from the policy guidelines section;
- A statement was added to the policy guidelines section regarding continuous positive airway pressure (CPAP) as preferred first-line treatment for most patients.

Spinal Cord Stimulation

Changes:

- One policy statement was re-phrased;
- Heart failure was added as an example of a condition for which spinal cord stimulation is investigational.

Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

Changes:

- Title was changed to *Stereotactic Radiosurgery and Stereotactic Body Radiotherapy*;
- Solitary or multiple brain metastases in patients having good performance status and no active systemic disease (defined as extracranial disease that is stable or in remission), were added as medically necessary indications under stereotactic radiosurgery;
- Patients with stage T1 or T2a non-small-cell lung cancer (not larger than 5 cm) showing no nodal or distant disease and who are not candidates for surgical resection, were added as medically necessary indications under for stereotactic body radiotherapy;
- One policy statement was changed with the addition of the word tremor as an example of a disorder for which treatment with stereotactic radiosurgery would be investigational;
- Additional information was added under the policy guidelines section regarding radiation source and number of brain metastatic lesions for which benefit may be achieved with stereotactic radiosurgery.

Total Artificial Hearts and Implantable Ventricular Assist Devices

For Medicare Advantage:

Section reorganized, clarifications include:

- Patient must be active on the Organ Procurement and Transplantation Network (OPTN) heart transplant wait list if ventricular assist device (VAD) is to be used for bridge to transplant;
- Clarification of situations not addressed by the policy such as VADs for right ventricular support, biventricular support, use in beneficiaries under the age of 18, use in beneficiaries with complex congenital heart disease, or use in beneficiaries with acute heart failure without a history of chronic heart failure.

Treatment of Varicose Veins/Venous Insufficiency

Changes:

- One policy statement was expanded to include microfoam sclerotherapy as medically necessary treatment of the greater, lesser and accessory saphenous veins;
- Corresponding changes were made to add microfoam sclerotherapy to the not medically necessary statement when criteria is not met and to the another policy statement to specify microfoam sclerotherapy as an exemption to sclerotherapy techniques which are considered investigational;

For Medicare Advantage:

- Pregnant women and persons on anticoagulation therapy were removed from the list of patients for whom sclerotherapy, ligation and/or stripping of varicose veins, or endovenous ablation therapy are not appropriate.

Vertebral Fracture Assessment With Densitometry

Medicare Advantage changes:

- A local coverage article was revised January 15, 2015 and therefore the Medicare Advantage medically necessary statement was re-stated;
- The investigational statement was removed for lack of support.

New Protocols

The effective date of these new protocols is July 1, 2015, unless otherwise indicated.

Artificial Pancreas Device Systems

- This Protocol was developed to address artificial pancreas device systems when this subject matter was removed from the *Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid* protocol;
- There is one medically necessary policy statement which includes criteria for use of an FDA-approved artificial pancreas device system with a low glucose suspend feature;
- There is one investigational policy statement addressing the use of artificial pancreas device system in all situations not meeting criteria;
- Preauthorization is required.

Endovascular Therapies for Extracranial Vertebral Artery Disease

- Endovascular therapy, including percutaneous transluminal angioplasty, with or without stenting, is considered investigational for the management of extracranial vertebral artery disease;
- Preauthorization is not required but is recommended if, despite this protocol position, the physician feels this service is medically necessary.

Gender Reassignment Surgery

- This is a local protocol, effective date May 1, 2015, formulated to ensure compliance with NYS mandate;
- The medically necessary policy statement includes criteria for all appropriate treatment indicated prior to gender reassignment surgery including mental health counseling, hormone therapy, and real life experience in the desired gender role;
- Medically necessary surgical procedures for gender reassignment are listed in the protocol;
- A not medically necessary policy statement addresses situations that do not meet the stated criteria;
- A second not medically necessary policy statement addresses surgical procedures that are intended to improve the gender-specific appearance of an individual (cosmetic);
- Preauthorization is required.

Genetic Testing for Marfan Syndrome, Thoracic Aortic Aneurysms and Dissections, and Related Disorders

- One policy statement indicates testing may be medically necessary when signs and symptoms of a connective tissue disorder are present, but a definitive diagnosis cannot be made using established clinical diagnostic criteria;
- A second medically necessary policy statement addresses individual, targeted mutation testing to assess future risk of disease in an asymptomatic individual when there is a known pathogenic mutation in the family;
- Testing must be done using panels comprised entirely of focused mutation testing limited to the following genes: *FBN1, MYH11, ACTA2*, *TGFBR1*, and *TGFBR2;*
- There is one investigational statement addressing testing for these cited conditions if not limited to focused mutation testing for the specific genes listed;
- Preauthorization is required.

Genetic Testing for PALB2 Mutations

- There is one investigational policy statement addressing genetic testing for *PALB2* mutations in patients with breast or pancreatic cancer or for cancer risk assessment in patients with or without a family history of breast or pancreatic cancer;
- Preauthorization is required.

Pharmacogenetic Testing for Pain Management

- Genetic testing for pain management is considered investigational for all indications;
- Preauthorization is required.

Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Allogeneic Hematopoietic Stem-Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms
- Allogeneic Pancreas Transplant
- Antigen Leukocyte Antibody Test
- Arthroscopic Débridement and Lavage as Treatment for Osteoarthritis of the Knee
- Artificial Intervertebral Disc: Cervical Spine
- Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions
- Automated Ambulatory Blood Pressure Monitoring for the Diagnosis of Hypertension in Patients With Elevated Office Blood Pressure
- BCR-ABL1 Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia
- Biofeedback as a Treatment of Chronic Pain
- Biofeedback as a Treatment of Fecal Incontinence or Constipation
- Biofeedback as a Treatment of Headache
- Catheter Ablation for Cardiac Arrhythmias
- Charged-Particle (Proton or Helium Ion) Radiation Therapy
- Cognitive Rehabilitation
- Confocal Laser Endomicroscopy
- Cooling Devices Used in the Outpatient Setting
- Dynamic Spinal Visualization
- Extracranial Carotid Angioplasty/Stenting
- Fetal Surgery for Prenatally Diagnosed Malformations
- Functional Neuromuscular Electrical Stimulation
- Genetic Testing for Cardiac Ion Channelopathies
- Genetic Testing for Familial Alzheimer Disease
- Genetic Testing for Predisposition to Inherited Hypertrophic Cardiomyopathy
- Genetic Testing for PTEN Hamartoma Tumor Syndrome
- Hematopoietic Stem Cell Transplantation for Breast Cancer
- Hematopoietic Stem Cell Transplantation for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma
- Hematopoietic Stem Cell Transplantation for Chronic Myelogenous Leukemia
- Hematopoietic Stem Cell Transplantation for Non-Hodgkin Lymphomas
- Hematopoietic Stem Cell Transplantation for Solid Tumors of Childhood
- Hematopoietic Stem Cell Transplantation in the Treatment of Germ-Cell Tumors
- Hematopoietic Stem-Cell Transplantation for Acute Myeloid Leukemia
- Intensity-Modulated Radiotherapy: Abdomen and Pelvis (Formerly Intensity-Modulated Radiation Therapy [IMRT]: Abdomen and Pelvis)
- Intensity-Modulated Radiotherapy: Central Nervous System Tumors (Formerly Intensity-Modulated Radiation Therapy [IMRT]: Central Nervous System Tumors)

- Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas or Metastasis to the Brain (Formerly Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas of the Brain)
- JAK2 and MPL Mutation Analysis in Myeloproliferative Neoplasms
- Laboratory Tests for Heart Transplant Rejection
- Liver Transplant
- Lung and Lobar Lung Transplant
- Manipulation Under Anesthesia
- Measurement of Exhaled Nitric Oxide and Exhaled Breath Condensate in the Diagnosis and Management of Asthma and Other Respiratory Disorders
- Microprocessor-Controlled Prostheses for the Lower Limb
- Nerve Graft in Association With Radical Prostatectomy
- Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease
- Oncologic Applications of Photodynamic Therapy, Including Barrett Esophagus
- Optical Coherence Tomography for Imaging of Coronary Arteries
- Optical Coherence Tomography of the Anterior Eye Segment
- Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders
- Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence
- Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy
- Postsurgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis
- Quantitative Assay for Measurement of HER2 Total Protein Expression and HER2 Dimers
- Small Bowel/Liver and Multivisceral Transplant
- Surgical Interruption of Pelvic Nerve Pathways for Primary and Secondary Dysmenorrhea
- Technology Assessment
- Thermography
- Transanal Radiofrequency Treatment of Fecal Incontinence
- Transcatheter Arterial Chemoembolization to Treat Primary or Metastatic Liver Malignancies
- Vertebral Axial Decompression
- Wearable Cardioverter Defibrillators

Deleted Protocols

Effective immediately, the following protocols are archived:

- Bone Morphogenetic Protein
- End-Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema
- Home Prothrombin Time Monitoring

Effective April 1, 2015, the following protocol is archived:

- Monitored Anesthesia Care (MAC) (see Stat Bulletin: *Medical Protocol Update: Monitored Anesthesia Care)*

The above are brief summaries. Please refer to the protocols posted on our provider website, for the details of the updated and new protocols that affect your practice. If you need help finding a specific protocol update, please contact Provider Service.